



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,383	12/22/2000	Peter Van Vlasselaer	4750-0001.30	9470

7590 07/07/2005
Denise M Kettelberger
P O Box 2903
Minneapolis, MN 55402-0903

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,383

Applicant(s)

VLASSELAER ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the remarks and amendment filed on 4/28/2005.

Claims 22 and 24 have been amended. Thus, claims 16-24 are under consideration.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103, maintained

3. The rejection of claims 16-24 under 35 USC 103(a) as being unpatentable over Huland et al. in view of both Debs et al. and Ruskewicz et al. further evidenced by Nayar et al or Hora et al. is maintained for reasons stated in the previous Office Action dated 1/13/03, 11/17/03 and 10/29/04. Applicant arguments have been fully considered but are deemed not to be persuasive. Specifically, claims 22 and 24 contains "comprising" language which is considered to be open because "Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." MPEP2163 II.B. Therefore, even if stabilizing agents are limited to sugar, alcohol, amino acid, or a combination thereof, and wherein the composition does not include serum albumin, the aqueous γ -IFN solution could still contain serum albumin.

Applicants appear to show nonobviousness of the instant invention by attacking the references individually. Specifically Applicants assert that Huland et al. does not teach aerosol composition having these limitations. As discussed extensively in the previous Office Action dated 10/29/2004 (pages 3-4), the Office notes the decision in *Swinehart and Sfiligoj*, 169 USPQ 226, in which it was found that mere recitation of a

Art Unit: 1647

newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art.

Although the prior art of Huland et al. did not necessarily appreciate the mechanism or describe the stability conferred by the salts, sugar and buffer on the cytokine it is an inherent property of these compounds in the composition. It is noted that specific statements in the references themselves that would spell out the claimed invention, are not necessary to show obviousness, since questions of obviousness involve not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See *CTS Corp. v. Electro Materials Corp. of America* 202 USPQ 22 (DC SNY 1979); and *In re Burckel* 201 USPQ 67 (CCPA 1979). Thus, the references of record when combined would make the instant invention obvious as a whole at the time it was made. Furthermore, contrary to Applicants assertion that it is the Applicants who have discovered that sugar, alcohol, amino acids or combinations thereof stabilizing proteins Office did provide evidentiary art of Nayar et al and Hora et al. that describe serum free stabilized protein. In addition, contrary to Applicants assertion that Nayar et al reference teaches away from the instant invention, the reference discusses the two coagulation factors and compares the stability. In fact, Nayar et al discuss the stabilization of recombinant human interleukin-1-receptor antagonist using methods similar to that disclosed in the reference (column 2, lines 46-50). Therefore, the rejection of record is maintained.

4. The rejection of claims 16-24 under 35 USC 103(a) as being unpatentable over Huland et al. and Jaffe et al. in view of both Debs et al. and Ruskewicz et al. further

Art Unit: 1647

evidenced by Nayar et al or Hora et al. is maintained for reasons stated in the previous Office Action dated 10/29/04. Applicants' arguments have been fully considered but are deemed not to be persuasive. Applicants' traverse the rejection essentially for the same reasons as stated. Thus, the rejection is maintained for reasons stated previously and above in paragraph 3.

Claim Rejections - 35 USC § 112, maintained.

5. The rejection of claims 22 and 24 under 35 USC 112, first paragraph as failing to comply with written description requirement is maintained for reasons stated in the previous Office Action dated 10/29/04. This is a new matter rejection. Since claim 15 has been cancelled, arguments pertaining to claim 15 will not be addressed. Applicants' arguments have been fully considered but are not considered to be persuasive. The Office maintains that the original claims did not specify the stabilizing agent and the dispersing agents used in the instant invention. Neither did the claims disclose that the serum albumin was excluded from the preparation. In addition, the specification also did not indicate that serum albumin was excluded from the preparation (see page 7 , lines 26-28). MPEP states that, A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement. See Gentry Gallery, 134 F.3d at 1480, 45 USPQ2d at 1503; In re Sus, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) ("[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any aryl or substituted aryl radical' would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically

Art Unit: 1647

substituted aryl radicals [i.e., aryl azides] would be suitable for such purposes.")

(emphasis in original) MPEP 2163 [R-2] IB. Thus, the Office maintains that the rejection of claims 22 and 24 under 35 USC 112, first paragraph as failing to comply with written description requirement.

6. No claims are allowed. However, claims if rewritten as consisting of a dispersing agent and stabilizing agent wherein the stabilizing agent consists of sugar, alcohol, amino acid or a combination thereof, maybe allowable.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 07/05


JANET ANDRES
PATENT EXAMINER